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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/855,797	05/16/2001	James L. Hartley	0942.285000G	2106
26111	7590	06/28/2006	EXAMINER	
STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			SCHLAPKOHL, WALTER	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 06/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/855,797	Applicant(s) HARTLEY ET AL.	
	Examiner Walter Schlapkohl	Art Unit 1636	<i>Waf</i>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 52-59, 61-68 and 71-78 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 52-59, 61-68 and 71-78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>4/11/2006</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of the papers filed 4/11/2006 in which claims 69-70 were cancelled. Claims 52-59, 61-68 and 71-78 are pending and under examination in the instant Office Action.

Any rejection made in the previous Office Action not recited herein is hereby withdrawn.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/11/2006 has been entered.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 52-58, 62 and 66-68 are rejected under 35 U.S.C. 102(b) as being anticipated by Boyd (*Nucleic Acid Research* 21(4):817-821, 1993; of record). **This rejection is maintained for reasons of record.**

Response to Arguments

Applicant argues that claims 52-59 and claims 61-68 recite methods that involve first contacting a linear nucleic acid with an adapter having a first site-specific recombination site to make an "adapterized" nucleic acid having one or more adapters at one or more termini, and then recombining the "adapterized" nucleic acids with a vector having a second site-specific recombination site. Applicant further argues that the Boyd reference teaches only *intramolecular* recombination of linear nucleic acids molecules and not *intermolecule* recombination. Applicant further argues that the Boyd reference does not

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anticipate claims 71-78 because the Boyd reference only teaches the synthesis of nucleic acid molecules having recombination sites that DO recombine with each other, whereas the claims recite two or more recombination sites that do not recombine with each other.

Applicant's arguments have been carefully considered and are respectfully found unpersuasive for the following reasons. First, Boyd teaches an *in vitro* method for synthesizing one or more nucleic acid molecules comprising one or more site-specific recombination sites, said method comprising three method steps as recited in the claims. The first and second method steps are "(a) obtaining at least one isolated linear nucleic acid;" and "(b) contacting said molecule *in vitro* with one or more adapters which comprise at least a first site-specific recombination site or portions thereof under conditions sufficient to add one or more of said adapters to one or more termini of said linear nucleic acid molecule." Boyd teaches this at, e.g., page 818, 2nd column, second full paragraph: "For turbo cloning, a plasmid vector containing a *lox* site must be used: linearized, blunt-ended vector (p9lox5) and fragment DNAs are ligated in 15% PEG at room temperature." As stated in the previous Office Action, Examiner has interpreted "adapter" to encompass the lox site-containing vectors taught by Boyd. The third method step is

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"(c) mixing said linear nucleic acid molecule with at least one vector comprising at least a second site-specific recombination site or portions there, *in vitro* in the presence of at least one site-specific recombination protein, under conditions sufficient to cause recombination between said first and second site-specific recombination sites, wherein said site-specific recombination protein mediates said recombination." Boyd teaches this step at, e.g., page 819, 1st column, first full paragraph, when he notes that a reaction mixture (comprising vectors and fragments) "is diluted to abolish macromolecular crowding and Cre protein added" (see also Figure 2 for all method steps). The claims do not limit the molecular interactions of the method steps to interactions which are either intermolecular or intramolecular. As long as Boyd teaches each of (a), (b) and (c), the claims are anticipated by Boyd.

Regarding Applicant's second argument, Examiner agrees with Applicant insofar as the Boyd reference does not anticipate claims 71-78 because the Boyd reference only teaches the synthesis of nucleic acid molecules having recombination sites that DO recombine with each other. For this reason, those claims were not rejected in the previous Office Action as

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anticipated by Boyd, as alleged by Applicant, and Applicant's argument is moot.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 61-65, 71-72, 74-76 and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyd (cited above) in view of Alonso et al (*FEMS Microbiology Letters* 142:1-10, 1996). **This rejection is maintained for reasons of record.**

Claims 59, 61-62, 71-73 and 75-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyd (cited above) in view of Waterhouse et al (*Nucleic Acids Research* **21**(9):2265-2266, 1993; of record). **This rejection is maintained for reasons of record.**

Response to Arguments

Applicant argues that claims 52-68 recite methods that involve the intermolecular recombination between an "adapterized" linear nucleic acid and a vector. Applicant further argues that claims 71-78 recite methods for making nucleic acid molecules having two or more site-specific recombination sites that do not recombine with each other. Applicant further argues that the trihybrid molecules disclosed by Boyd are specifically designed and are suitable only for intramolecular recombination, and cannot be used for the intermolecular recombination methods recited in claims 52-68. Applicant further argues that the teachings of Boyd are directly

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opposite to the presently claimed invention, specifically because Boyd teaches intramolecular recombination and the claimed methods recite intermolecular recombination.

Applicant's arguments have been carefully considered and are respectfully found unpersuasive. The arguments regarding Boyd have been addressed above in the response to arguments regarding the rejection under 35 U.S.C. § 102. Briefly, the claims do not recite the limitation that the recombination occurs intermolecularly. Neither does the Boyd reference limit the use of the nucleic acids to intramolecular interactions. Furthermore, as noted in the rejection made in the previous Office Action, Alonso et al explicitly note that the Int family recombinases "catalyse recombination between sites located either in separate DNA molecules (integration) or in the same DNA molecule (resolution and inversion)" (see Alonso et al at page 1, 2nd column, first full paragraph).

Conclusion

No claim is allowed.

Certain papers related to this application may be submitted to the Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94

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(December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is (571) 273-8300. Note: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent applications to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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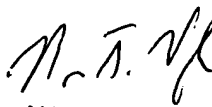
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Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Walter Schlapkohl whose telephone number is (571) 272-4439. The examiner can normally be reached on Monday through Thursday from 8:30 AM to 6:00 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached at (571) 272-0781.

Walter A. Schlapkohl, Ph.D.
Patent Examiner
Art Unit 1636

June 14, 2006


NANCY VOGEL
PRIMARY EXAMINER